Bar Pedicle Screw Spinal Fixation System

510(k) Summary

JUL 26 2006

July 25, 2006

Submitter:
Applied Spine Technologies, Inc.
300 George St.
New Haven, CT 06511

Contact Person: Michele Lucey

Trade Name: BAR Pedicle Screw Spinal Fixation System

Common Name: Posterior Pedicle Screw System

Classification Name: Class II per 21 CFR Section 888.3070

Product Code: MNI/MNH

Equivalent Devices:
Dynesys® Dynamic Stabilization System (K031511)
Manufactured and distributed by:
Zimmer, Inc.

ISOBAR TTL Semi-Rigid Pedicle Screw Fusion System (K990118)
SCIENT'X USA

CD Horizon® Spinal System (K043488)
Medtronic Sofamor Danek

Device Description:
The BAR Pedicle Screw Fixation System consists of pedicle screws, rods, and connectors. It can be used for single level fixation. All components are manufactured from titanium (ASTM F-67), titanium alloy (ASTM F-136), Cobalt Chromium Molybdenum alloy (ASTM F-1547.

The system consists of pedicle screw anchors which are inserted into the pedicle, a connector that has a ball and socket feature that connects to the pedicle screws. The ball and socket feature which allows for adjustment during implantation. The motion allowed by the ball and socket serves to offload the pedicle screws and distribute the stress across the vertebral body. The connector also contains a clamping mechanism which clamps the rigid rod into place.

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Intended Use:

The BAR Pedicle Screw Spinal Fixation System is intended for posterior non cervical pedicle screw fixation in the lumbo-sacral spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar or sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition the BAR Pedicle Screw Spinal Fixation System, used as a pedicle screw fixation system is intended for:

a. Patients receiving only autogenous bone graft.
b. Patients having the device fixed or attached to the lumbar and sacral spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.

Summary Nonclinical Tests:

Testing was performed per ASTM F1717 and the results are comparable to the predicate devices.

Basis for Substantial Equivalence:

The BAR Pedicle Screw Spinal Fixation System has similar design characteristics, i.e. material, screw size, rod based, clamping connection mechanisms, and indications as the ISOBAR TTL Spinal System (k990119) and the Dynesys Dynamic Stabilization System (k031511). All three systems stabilize the spine to support fusion while allowing some motion or flexibility which serve to distribute loads across the segment being fused.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2006

Applied Spine Technologies, Inc.
% Ms. Michele Lucey
Vice President, Regulatory Affairs
and Quality Assurance
300 George Street, Suite 511
New Haven, Connecticut 06511

Re: K061162
Trade/Device Name: BAR Pedicle Screw Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: June 13, 2006
Received: June 19, 2006

Dear Ms. Lucey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061162

Device Name: **BAR** Pedicle Screw Spinal Fixation System

Indications for Use:

Intended Use/Indications for Use

The BAR Pedicle Screw Spinal Fixation System is intended for posterior non cervical pedicle screw fixation in the lumbo-sacral spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar or sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition the BAR Pedicle Screw Spinal Fixation System, used as a pedicle screw fixation system is intended for:

a. Patients receiving only autogenous bone graft.
b. Patients having the device fixed or attached to the lumbar and sacral spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.

Warning

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Precautions

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Prescription Use _____ AND/OR ~~Over-The Counter Use~~ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061162